

7. What Is EPA's Position Regarding Environmental Management Systems?

The Agency supports the voluntary adoption of environmental management systems (EMSs) by CAFOs. On May 15, 2002, the Administrator announced the Agency's Position Statement on Environmental Management Systems. This statement outlines the policy and principles by which the Agency will work with industry to promote the use of EMSs to improve environmental protection. EPA promotes the widespread use of EMSs across a range of organizations and settings, with particular emphasis on adoption of EMSs to achieve improved environmental performance and compliance, and pollution prevention through source reduction. The Agency encourages organizations to implement EMSs based on the plan-do-check-act framework, with the goal of continual improvement. An organization's EMS should address its entire environmental footprint (everywhere it interacts with the environment both negatively and positively), including both regulated and unregulated impacts, such as energy and water consumption, dust, noise, and odor. EPA supports EMSs that are appropriate to the needs and characteristics of specific sectors and facilities.

An operation could choose to implement an EMS that could include a CNMP, but would also include policies and practices designed to address other significant environmental problems. EPA, as part of its overall policy on EMSs, supports adoption of these systems in a variety of sectors, including agriculture. EPA has worked with specific agricultural producer groups like the United Egg Producers to develop a voluntary EMS program. USDA is also funding a major effort through the University of Wisconsin called *Partnerships for Livestock Environmental Assessment Management Systems*. This project is designed to provide information and other guidance on ways to use EMSs effectively in a variety of agricultural settings. EPA serves on the Advisory Committee for this effort, along with USDA and other federal agencies.

In the 2001 Notice, EPA outlined options for how an EMS program may be incorporated into the rule. These options were based on ISO 14000 criteria, an international standard. EPA received a number of comments on these options. Industry was split in support of EMS: some groups thought that use of EMSs in the proposal exceeded authorities provided under the Clean Water Act, whereas others

welcomed EMSs as an alternative to co-permitting. Environmental groups were concerned that reliance on EMS constituted a roll-back of rule requirements.

EPA is not including an EMS as an option in this final rule. EPA recognizes, based on comments, that offering an EMS alternative made the rule more complex and was not entirely consistent with the Agency's goal to keep the rule simple, easy to understand and easy to implement. However, EPA supports the use of EMS by States, as appropriate. In today's rule, EPA is requiring that CAFOs develop and implement nutrient management plans that can help CAFOs manage manure and protect water quality. CAFOs may want to consider implementation of nutrient management plans as part of a broader EMS to manage the specific impacts of excess nutrients. The CAFO's EMS would be broader than just a nutrient management plan, however, and would cover all media and both regulated and unregulated aspects.

More information on EPA's EMS policy, along with sector-specific EMS templates and guidance is provided at www.epa.gov/ems.

B. How Is EPA Coordinating With Other Federal Agencies?

EPA and USDA are committed to working together to provide coordinated assistance to animal agriculture for the betterment of animal agriculture and the environment. The agencies are working together to educate farmers, suppliers, USDA field representatives, consultants, and others on these new regulations. Both EPA and USDA believe in the importance of providing education, training and technical assistance to all involved in animal agriculture that can play a role in helping farmers understand the new requirements and how they can meet them. EPA and USDA have different roles and different constituencies. EPA sets the requirements, works toward compliance by industry, and enforces against noncompliance. USDA provides technical assistance, education, and training to farmers, growers, and allied industries. This education, training, and technical assistance will be vitally important to CAFO operators as they work to come into compliance with the new regulations. The Natural Resource Conservation Service and the Cooperative State Research, Education, and Extension Service are the key USDA agencies that will work with farmers to educate them on the requirements of the EPA CAFO rule. USDA will continue to educate EPA personnel on the intricacies of animal agriculture so that

the Agency can improve its communication with this vital sector.

There was significant comment on the proposed rule on how EPA and USDA should work together with farmers to implement this rule. Some thought the implementation should be left to USDA NRCS and CSREES. Others thought EPA and USDA should work together in the field in a coordinated effort to educate, regulate and assist AFOs and CAFOs. One commenter suggested that EPA monitor water quality and NRCS provide technical assistance. A few comments asked that EPA join other federal agencies and conduct a comprehensive examination of the problems generated by CAFOs.

EPA and USDA believe that only by working in close partnership will the federal government provide the best service to farmers and the rest of the American public. It is EPA's intent and commitment to communicate and coordinate effectively across Agencies and Departments. Animal agriculture is important to this country, as is a sound, healthy environment. EPA and USDA believe these two goals can be jointly achieved.

X. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines a "significant regulatory action" as one that is likely to result in a rule that may:

1. Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;
2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is a "significant regulatory action" under the terms of Executive Order 12866. As such, this action was submitted to OMB for review. Changes

made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2040-0250.

The information collection requirements affect operations that are defined or designated as CAFOs under the final rule and, therefore, are subject to the record keeping, data collection, and reporting requirements associated with applying for and complying with an NPDES permit. They also affect the 43 States with approved NPDES programs that administer NPDES permits for CAFOs ("approved States"). EPA and approved States use the information routinely collected through NPDES permit applications and compliance evaluations in the following ways: to issue NPDES permits with appropriate limitations and conditions that comply with the Clean Water Act; to update information in EPA's databases that permitting authorities use to determine permit conditions; to calculate national permit issuance, backlog, and compliance statistics; to evaluate national water quality; to assist

EPA in program management and other activities that ensure national consistency in permitting; to assist EPA in prioritizing permit issuance activities; to assist EPA in policy development and budgeting; to assist EPA in responding to Congressional and public inquiries; and to ensure compliance with the terms and conditions of the permit.

The responses to the information collection requirements are mandatory for CAFOs. CAFOs are defined as point sources under the NPDES program (33 U.S.C. 1362). Under 33 U.S.C. 1311 and 1342, a CAFO must obtain an NPDES permit and comply with the terms of that permit, which include appropriate record keeping and reporting requirements. Furthermore, 33 U.S.C. 1318 provides authority for information collection (*i.e.*, record keeping, reporting, monitoring, sampling, and other information as needed), which applies to point sources. Approved States will also incur burden for record keeping, data collection, and reporting requirements when they revise and implement any program changes necessitated by the final rule. Under 40 CFR 123.62(e), State NPDES programs must at all times be in compliance with federal regulations.

CAFOs must develop their nutrient management plans, retain them onsite, and make them available to the

permitting authority on request. These plans may contain confidential business information. When this is the case, the respondent can request that such information be treated as confidential. All confidential data will be handled in accordance with 40 CFR 122.7, 40 CFR Part 2 (40 CFR 2.201 *et seq.*), and EPA's Security Manual Part III, Chapter 9, dated August 9, 1976.

EPA estimates that the average annual public burden for this rule making will be 1.9 million hours. This estimate includes 0.3 million hours for State respondents and 1.6 million hours for CAFO respondents. It includes the time required to review instructions, search existing data sources, gather and maintain all necessary data, and complete and review the information collection. Table 10.1 provides the breakdown of these estimates by type of response. Average annual capital and O&M costs will total \$5.9 million. This estimate includes \$1.3 million in CAFO capital costs to purchase sampling equipment, install depth markers, and purchase services for the engineering portion of the nutrient management plan. Average annual CAFO O&M costs of \$2.9 million include laboratory analyses of soil and manure samples, tractor rental, and record keeping costs. Average annual State O&M costs of \$1.7 million pay for public notifications.

TABLE 10.1.—BURDEN ESTIMATES PER RESPONSE

Activities	Response frequency	Average annual burden (hours)	Average annual responses ¹	Labor cost (\$ millions)
CAFO Respondents				
Start-up Activities	One time	14,493	4,831	\$0.32
Permit Application Activities and NOIs	Every 5 years	43,479	4,831	0.95
ELG and NPDES Data Collection and Record Keeping Activities:				
Visual inspections	Annual	152,260	11,712	1.67
Equipment inspection	Annual	32,238	8,060	0.35
Manure sampling	Annual	26,088	11,712	0.29
Soil sampling	Every 5 years	31,057	3,613	0.34
ELG and NPDES record keeping	Annual	936,982	11,712	10.31
Additional NPDES Record Keeping and Reporting Activities:				
Nutrient management plan	Every 5 years	250,168	4,831	9.06
Manure transfer record keeping	Annual	102,858	7,347	1.13
Annual report	Annual	11,712	11,712	0.26
Compliance inspections	Per inspection	9,370	2,342	0.20
State Respondents				
NPDES Program Modification Activities	One time	3,583	14	0.11
General Permit Activities	Annual	31,598	3,277	0.94
Individual Permit Activities	Annual	174,143	1,573	5.19
Compliance Evaluation:				
Inspections	Annual	36,317	2,270	1.08
Annual Reports	Annual	45,397	11,349	1.35

¹ For CAFOs, the number of respondents for each type of response equals the number of responses. For approved States, these estimates differ. There are 43 approved States responding to the information collection requirements, but the number of responses for some activities can be greater because the estimate depends on the number of CAFOs submitting information or undergoing inspections. EPA is the permitting authority for some CAFOs, so the response estimates for CAFOs and States will differ.

These burden and cost estimates have been updated since the proposed rule to reflect changes in the final rule. The Agency received only a few comments on the PRA section of the preamble for the proposed rule. Most commenters believed that the number of affected operations was underestimated. EPA revised its estimate of total AFO operations and its estimate of affected CAFO operations. The final rule requirements results in fewer CAFOs compared to the proposed rule estimates.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15. EPA is amending the table in 40 CFR Part 9 of currently approved ICR control numbers issued by OMB for various regulations to list the information requirements contained in this final rule.

C. Regulatory Flexibility Act

1. Background

The RFA generally requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as (1) A small business based on annual revenue standards established by the Small Business Administration (SBA), with the

exception of one of the six industry sectors where an alternative definition to SBA's is used; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

For purposes of assessing the impacts of today's rule on small entities in the egg-laying sector, EPA considered small entities in this sector as an operation that generates less than \$1.5 million in annual revenue. A summary of EPA's rationale and supporting analyses pertaining to this alternative definition is provided in the record and in section 4 of the *Economic Analysis*. See discussion under "Use of Alternative Definition" later in this section. Because this definition of small business is not the definition established under the RFA, EPA proposed using this alternative definition in the **Federal Register** and sought public comment. See 66 FR 3099. EPA also consulted with SBA Chief Counsel for Advocacy on the use of this alternative definition.

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule and convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations of representatives of affected small entities in accordance with section 609(b) of the RFA. See 66 FR 3121–3124; 3126–3128 (January 12, 2001). A detailed discussion of the SBAR Panel's advice and recommendations can be found in the *Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule on National Pollutant Discharge Elimination System and Effluent Limitations Guideline Regulations for Concentrated Animal Feeding Operations*, April 7, 2000. This document is included in the public record (DCN 93001). The 2001 proposal provides a summary of the Panel's recommendations. (See 66 FR 3121–3124).

As required by section 604 of the RFA, EPA prepared a final regulatory flexibility analysis (FRFA) for today's final rule. The FRFA addresses the issues raised by public comments on the IRFA, which was part of the proposal for this rule. The FRFA is available for review in the docket and is summarized below.

2. Summary of Final Regulatory Flexibility Analysis

As required by section 604 of the RFA, EPA also prepared a final regulatory flexibility analysis (FRFA) for today's rule. The FRFA addresses the issues raised by public comments on the IRFA, which was part of the proposal of this rule. The FRFA is available for review in the docket (in section 4 of the final *Economic Analysis*). A summary is provided below.

a. Need for and objectives of the regulations. A detailed discussion of the need for the regulations is presented in section IV of the 2001 preamble (66 FR 2972–2976). A summary is also provided in section 4 of the final *Economic Analysis*. In summary, EPA's rationale for revising the existing regulations include the following: address reports of continued discharge and runoff from livestock and poultry operations in spite of the existing requirements; update the existing regulations to reflect structural changes in these industries over the past few decades; and improve the effectiveness of the existing regulations. A detailed discussion of the objectives and legal basis for the rule is presented in sections I and III of the proposal preamble (66 FR 2959).

b. Significant Comments on the IRFA. The significant issues raised by public comments on the IRFA address exemptions for small businesses, disagreement with SBA definitions and guidance on how to define small businesses for these sectors, and general concerns about EPA's financial analysis and whether it adequately captures potential financial effects on small businesses.

Commenters generally recommend that EPA exempt all small businesses from regulation, arguing in some cases that regulating small businesses could affect competition in the marketplace, discourage innovation, restrict improvements in productivity, create entry barriers, and discourage potential entrepreneurs from introducing beneficial products and processes. Several commenters claimed that EPA had misrepresented the number of small businesses. In particular, several commenters objected to SBA's small business definition for dairy operations, claiming it understates the number of small businesses in this sector. One commenter claimed that EPA's estimate of the total number of operations is understated and therefore must understate the number of small businesses. Some commenters objected to the consideration of total farm-level revenue to determine the number of

small businesses since this understates the number of small businesses (despite SBA guidance, which bases its definitions on total entity revenue for purposes of defining a small business). However, other commenters claimed that EPA's approach to its small business analysis does not only capture operations that are, in fact, small businesses but also larger corporate operations. Another commenter recommended that EPA simply consider any operation with fewer than 1,000 animal units a small business. EPA also received comments requesting that EPA consider use of regional-specific definitions of small business because of concerns that the revenue-based SBA definition might not be applicable to operations in Hawaii since producers in that State generally face higher cost of production and also higher producer prices relative to revenue and cost conditions at farms in the contiguous 48 States. Comments from SBA recommended that EPA adopt the Panel's recommendation not to consider changing the designation criteria for operations with fewer than 300 animal units as a means to provide relief to small businesses. SBA also recommended that EPA adopt the SBAR Panel's approach and allow permitting authorities to focus resources where there is greatest need. Finally, some commenters generally questioned the results of EPA's financial analysis, giving similarly stated concerns about EPA's financial data and models used for its main analysis.

In response, EPA notes that the projected impacts of today's final regulations on small businesses are lower than the projected impacts of the proposed rule. For example, the final rule does not extend the effluent guideline regulations to Medium CAFOs, as was proposed in the 2001 proposal. Instead, EPA is retaining the existing regulatory threshold, applying the effluent guideline to Large CAFOs only. Requirements for Medium CAFOs will continue to be subject to the BPJ requirements as determined by the permitting authority, thus requiring that fewer small businesses adopt the effluent guideline standards. More information on this topic is available in section IV of this preamble. Section IV discusses other regulatory changes since the 2001 proposal, indicating greater alignment with SBAR Panel recommendations. Refer to section IV of this preamble for more information on the comments and EPA's responses to those comments, as well as EPA's justification for final decisions on these options.

Regarding EPA's estimate of the number of small businesses, the Agency continues to follow SBA guidance and SBA definitions on how to define small businesses for these sectors. However, EPA has made substantial changes to the financial data and models used for its main analysis, which is also used to evaluate financial effects on small businesses. Both the 2001 Notice (66 FR 58556) and the 2002 Notice (67 FR 48099) describe the public comments received by EPA on the baseline financial data and the methodological approach developed by EPA to evaluate financial effects. These comments and how EPA has addressed them are discussed more fully in section 4 of the final *Economic Analysis*. EPA's detailed responses to comments, and the comments themselves, are contained in the *Comment Response Document* in response categories SBREFA and Small Business.

c. Description and estimation of number of small entities to which the regulations will apply. The small entities subject to this rule are small businesses. No nonprofit organizations or small governmental operations operate CAFOs. As discussed in section VIII.B.1(c) of this preamble, to estimate the number of small businesses affected by this final rule, EPA relied on the SBA size standards for these sectors, with the exception of size definitions for the egg sector. SBA defines a "small business" in these sectors as an operation with average annual revenues of less than \$0.75 million for dairy, hog, broiler, and turkey operations; \$1.5 million in revenue for beef feedlots; and \$9.0 million for egg operations. The definitions of small business for the livestock and poultry industries are in SBA's regulations at 13 CFR 121.201. For this rule, EPA proposed and solicited public comment on and is using an alternative definition for small business for egg-laying operations. EPA defines a "small" egg laying operation for purposes of its regulatory flexibility assessments as an operation that generates less than \$1.5 million in annual revenue. EPA consulted with SBA on the use of this alternative definition, as documented in the rulemaking record for the 2001 proposal. Given these definitions, EPA evaluates "small business" for this rule as an operation that houses or confines fewer than 1,400 fed beef cattle (includes fed beef, veal, and heifers); 300 mature dairy cattle; 2,100 market hogs; 37,500 turkeys; 61,000 layers; or 375,000 broilers. The approach used to derive these estimates is described in

the *Economic Analysis* and in the record.

Using these definitions and available data from USDA and industry, EPA estimates that 6,200 of affected CAFOs across all size categories are small businesses. Among Large CAFOs, EPA estimates that about 2,330 operations are small businesses. Among Medium CAFOs, EPA estimates that about 3,870 operations are small businesses. Table 8.3 in section VIII of this preamble shows EPA's estimates of the number of regulated small businesses across all industry sectors. Section VIII.B.1(c) provides more detail on the estimated financial effects on small businesses under the final rule.

d. Description of the reporting, record-keeping, and other compliance requirements. Today's rule would require all AFOs that meet the CAFO definition to apply for a permit, develop and implement a nutrient management plan, collect and maintain records required by applicable technology-based effluent discharge standards, and submit an annual report to the responsible NPDES permitting authority. (No nonprofit organizations or small governmental operations operate CAFOs.) All CAFOs would also be required to maintain records of off-site transfers of manure. Record-keeping and reporting burdens include the time to record and report animal inventories, manure generation, field application of manure (amount, method, date, weather conditions), manure and soil analysis results, crop yield goals, findings from visual inspections of feedlot areas, and corrective measures. Records may include manure spreader calibration worksheets, manure application worksheets, maintenance logs, and soil and manure test results. EPA believes the owner/operator has the skills necessary to keep these records and make reports to the permitting authority.

Section X.B further summarizes the expected reporting and record-keeping requirements under the final regulations based on information compiled as part of the ICR for the Final NPDES and ELG Regulatory Revisions for Concentrated Animal Feeding Operations (EPA ICR No. 1989.01) prepared by EPA.

e. Steps taken to minimize significant impacts on small entities. In today's final rulemaking, EPA has adopted an approach for a regulatory program that mitigates impacts on small business, recognizes and promotes effective non-NPDES State programs, and works in partnership with USDA to promote environmental stewardship through voluntary programs, and financial and technical assistance. EPA's proposal

included many options that were not finally adopted in deference to these principles.

Because of the estimated impacts on small entities EPA is not certifying that this rule will not impose a significant impact on a substantial number of small entities. EPA has complied with all RFA provisions and conducted outreach to small businesses, convened a SBAR panel, prepared an Initial Regulatory Flexibility Analysis (IRFA) and a Final Regulatory Flexibility Analysis (FRFA), and also prepared an economic analysis. The Agency's actions include the following efforts to minimize impacts on small businesses:

- Retained structure of existing regulations, which allows EPA and states to focus on the largest producers;
- Retained applicability of effluent guidelines for Large CAFOs only;
- Retained existing designation criteria and process;
- Retained existing definition of an AFO;
- Retained conditions for being defined as a Medium CAFO;
- Eliminated the "mixed" animal calculation for operations with more than a single animal type for determining which AFOs are CAFOs;
- Raised the duck threshold for dry manure handling duck operations; and
- Adopted a dry-litter chicken threshold higher than proposed.

EPA went to some length to explore and analyze a variety of ELG regulatory alternatives to minimize impacts on small businesses. The record for today's rule includes extensive discussions of the alternatives, EPA's analysis of those alternatives, and the rationale for the Agency's decisions. In large part, the Agency incorporated most of the alternative considerations to reduce the burden to small businesses. By way of example, today's regulations will affect fewer small businesses at significantly reduced costs, as compared to the estimates of the number of small businesses and expected costs to those businesses based on the requirements set forth in the 2001 proposal. For more information on EPA's option selection rationale, see section IV of this preamble.

3. Compliance Guide

As required by section 212 of SBREFA, EPA is also preparing a small entity compliance guide to help small businesses comply with this rule. To request a copy, contact one of the persons identified in the **FOR FURTHER INFORMATION CONTACT** section at the beginning of this preamble. EPA expects that the guide will be available in March 2003.

4. Use of Alternative Definition

The RFA defines small entities as including small businesses, small governmental jurisdictions, and small organizations. The statute provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 U.S.C. 601(3)–(5). In addition to the above, to establish an alternative small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

As stated above, EPA proposed defining "small entity" for purposes of its regulatory flexibility assessments under the RFA as an operation that generates less than \$1.5 million in annual revenue. The Agency also consulted with SBA Chief Counsel for Advocacy. See 66 FR 2959, (January 12, 2001).

EPA received two comments from the same commenter requesting that EPA not use the alternative definition for egg-laying operations but instead consider regional-specific conditions for determining the number of small businesses. The commenter expressed concern that SBA's revenue-based definition might not be applicable to operations in Hawaii since producers in that State generally face higher cost of production and also higher producer prices relative to revenue and cost conditions at farms in the contiguous 48 States. There are a number of reasons why EPA did not use a regional-specific definition of small business for egg operations. First, consistent with the RFA, EPA uses small business definitions as defined by the SBA except in cases where EPA consults with the SBA Chief Counsel for Advocacy. Since size standards set by the SBA do not vary by region, EPA follows SBA's lead. Second, the regulations set requirements by the number of animal units at a farm, not the revenues associated with those animal units. An 82,000 bird egg-laying operation in the Midwest will be subject to the same effluent limitations guidelines as a 82,000 bird egg-laying operation in Hawaii and the territories. Third, the economic analysis, uses a representative farm approach. Only the broadest regional information could be obtained through USDA and other sources. Although some small subregions or localities might face unique issues, without performing a Section 308 survey of all regulated entities EPA must rely on the

representative farm approach. (*See also* response to comment DCN CAFO201246–C–6 regarding EPA's use of a representative farm approach, which is consistent with longstanding practices at USDA and the land grant universities.) Note however, that although EPA uses a single definition of small business across all regions, EPA's representative farm analysis of small business impacts does account for some regional variation in costs and revenues. Fourth, very few impacts are seen in the egg-laying sector, regardless of size. Even if EPA had classified the majority of egg-laying operations with less than 1,000 AU as small businesses, this would not have changed the outcome of the Agency's small business analysis in any material way. Finally, even if EPA were to classify all operations as small businesses in areas outside the contiguous 48 States (including Hawaii and Alaska), this would only raise the total number of small business by less than 10 operations. See response to comment DCN CAFO NODA 600053–5 regarding EPA's consideration of regional-specific definition of small business for the regulated sectors.

Today, EPA is establishing this alternative definition of "small entity" for the egg-laying sector for purposes of the regulatory flexibility analysis for this rule.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, established requirements for federal agencies to assess the effects of their regulatory actions on State, Tribal and local governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "federal mandates" that may result in expenditures to State, Tribal and local governments, in the aggregate, or to the private sector, of \$100 million or more in any one year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative

was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with regulatory requirements.

EPA has determined that this rule contains a federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. EPA revised the unfunded mandates analysis for State costs based on comments received. EPA expanded the categories of costs and increased the unit costs and hour burden while the final rule significantly decreased the number of potential permittees. Because the revisions were largely offsetting, there is little change in the overall burden estimated (\$8 million annually at proposal and \$9 million annually for the final rule). Accordingly, EPA has prepared under section 202 of the UMRA a written statement, which is summarized below. See section 5 of the *Economic Analysis* for the complete section 202 statement.

1. Private Costs

This statement provides quantitative cost-benefit assessment of the federal requirements imposed by today's final rules. In large part, the private sector, not other governments, will incur the costs. EPA estimates total compliance costs to industry of \$326 million per year (pre-tax, 2001 dollars). EPA estimates that the monetized benefits of the final regulations range from \$204 million to \$355 million annually. Section VIII.C.1 of this preamble provides additional information on EPA's analysis. The analysis is provided in section 5 of the *Economic Analysis* and other supporting information is provided in the *Benefits Analysis* supporting the final regulations. Both of these support documents are available in the administrative record for this rulemaking. A summary of these analyses is provided in section's VII and VIII of today's preamble.

2. State Local and Tribal Government Costs

Authorized States are expected to incur costs to update their State NPDES programs to conform to the final rule and implement the revised standards through issuing NPDES permits and inspecting CAFOs to ensure compliance. The total average annual State administrative cost to implement the permit program, approximately \$9 million, will not exceed the thresholds established by the UMRA. The analysis underlying this cost estimate is in the *NPDES Technical Support Document* found in the rule record. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect local or Tribal governments. There are no local or Tribal governments authorized to implement the NPDES permit program and the Agency is unaware of any local or Tribal governments who are owners or operators of CAFOs. Thus today's rule is not subject to the requirements of Section 203 of UMRA.

3. Funding and Technical Assistance Available to CAFOs

The 2002 Farm Bill authorized cost-share funding for six years (2002 through 2007) for EQIP. Funding starts at \$400 million in 2002 and continually increases to \$1.3 billion in the last year. Sixty percent of this funding is to be targeted to animal agriculture, including large and small feedlots, as well as pasture and grazing operations. An operation is eligible for a total of up to \$450,000 over the six year time frame. This funding is open to both CAFOs and AFOs. Being defined as a CAFO does not make you ineligible for this funding.

4. Funding Available to States

States may be able to use existing sources of financial assistance to revise and implement the final rule. Section 106 of the Clean Water Act authorizes EPA to award grants to States, Tribes, intertribal consortia, and interstate agencies for administering programs for the prevention, reduction, and elimination of water pollution. These grants may be used for various activities to develop and carry out a water pollution control program, including permitting, monitoring, and enforcement. Thus, State and Tribal NPDES permit programs represent one type of State program that can be funded by section 106 grants.

Key comments received on Unfunded Mandates relate to the increased cost to farmers and States and the need for funds for CAFO compliance and State permitting. In the discussion above,

EPA outlines the funding available to CAFO owners (EQIP) and to States (CWA section 106 grants) to help meet this rule's mandates.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 19, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This rule does not have Federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. EPA does not consider an annual impact of approximately \$9 million on States a substantial effect. In addition, EPA does not expect this rule to have any impact on local governments.

Further, the revised regulations would not alter the basic State-federal scheme established in the Clean Water Act under which EPA authorizes States to carry out the NPDES permitting program. EPA expects the revised regulations to have little effect on the relationship between, or the distribution of power and responsibilities among, the federal and State governments. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA's policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed rule from State and local officials.

During public comment, EPA received comments on its analysis required under the Federalism Executive Order. The comments were that the Agency had underestimated the cost impacts of the rule on States. In response to these comments, EPA reanalyzed the impacts on States.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with

Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.”

This final rule does not have Tribal implications. It will not have substantial direct effects on Tribal governments, on the relationship between the federal government and Indian Tribes, or on the distribution of power and responsibilities between the federal government and Indian Tribes, as specified in Executive Order 13175. First, no Tribal governments have been authorized to issue NPDES permits. Second, few CAFO operations are located on Tribal lands. Accordingly, the requirements of Executive Order 13175 do not apply to this rule.

Although Executive Order 13175 does not apply to this rule, EPA has briefed Tribal communities about this rulemaking at the National Environmental Justice Advisory Committee meeting in Atlanta, Georgia in June, 2000 and through notices in Tribal publications. In addition, EPA Regional Offices discussed this rulemaking with the Tribes in their regions.

During the public comment period, the Agency received no comments from Tribes or comments relating to tribal issues.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be “economically significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is subject to Executive Order 13045 because it is an economically regulatory action as

defined by Executive Order 12866, and we believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of increased nutrients, pathogens, and metals in surface water on children. The results of this evaluation are contained in the proposed *Environmental Assessment*, which is part of the public record for this final rule.

EPA has established a maximum contaminate level for nitrates in drinking water at 10 micrograms/liter. There is some evidence that infants under the age of six months may be at risk from methemoglobinemia caused by nitrates in private drinking water wells when ingesting water at nitrate levels higher than 10 micrograms/liter. The Agency has estimated the reduction in the number of households that will be exposed to drinking water with nitrate levels above 10 micrograms/liter in Chapter 8 of the *Benefits Assessment* (noting that the Agency does not have information on the number of households exposed to nitrates that also have infants). The Agency estimates that there are approximately 13.5 million households with drinking water wells in counties with animal feeding operations. Of these, the Agency estimates that approximately 1.3 million households are exposed to nitrate levels above 10 micrograms/liter. The Agency further estimates that approximately 112,000 households would have their nitrate levels brought below 10 micrograms/liter under the requirements of this final rule. The Agency estimates that options more stringent than these would provide only small incremental changes in pollutant loadings to groundwater (see the *Technical Development Document*). The Agency therefore does not believe that requirements more stringent than these in the rule would provide meaningful additional protection of children’s health risks from methemoglobinemia.

The Agency received no comments on the impacts to children’s health.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

The rule is not a “significant energy action” as defined in Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. EPA has concluded that this rule is not likely to have any adverse energy

effects. While there will be a minor increase in energy use from increased hauling of manure to offsite locations, EPA has estimated the increased fuel usage associated with transporting manure, litter, and other process wastewaters off site is approximately 423,000 barrels annually for all CAFOs. EPA does not believe that this will have a significant impact on the energy supply.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), (Pub L. 104–113 section 12(d), 15 U.S.C. 272 *note*) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking does involve the use of technical standards. In this rulemaking, EPA has developed regulatory standards for controlling pollutant discharges from permitted CAFOs based on its expertise, professional judgment, and the extensive record developed, in part, through the APA’s notice and comment process. While we identified the American National Standards for Good Environmental Livestock Production Practices, developed by the National Pork Producers Council and certified by ANSI as an American National Standard on February 20, 2002 (GELPP 0001–2002; 0002–2002; 0003–2002; 0004–2002; 0005–2002), and a commenter has identified ANSI/ASCE 7–98, a separate voluntary consensus standard, as being potentially applicable, we have decided not to use them in this rulemaking. The use of these voluntary consensus standard would have been impractical because EPA’s rule establishes a regulatory framework in which decisions as to what specific best management practices must be applied at individual animal feeding operations is generally left to the State in the exercise of its authority to issue NPDES permits. In issuing permits, States may consider these ANSI-certified standards and include, or not include, various elements as they may deem appropriate. It would not have been consistent with

EPA's design for this rule to adopt these ANSI-certified standards as national minimum requirements for all States to incorporate into all permits for covered animal feeding operations. EPA received a number of comments suggesting that EPA should specifically include the GELPPs and ANSI/ASCE 7-98 as authorized alternative management standards in the final CAFO rule. EPA decided not to do so for the reasons discussed above.

In any event, it is important to note that the standards set out in this rule may be better characterized as representing regulatory decisions EPA is directed to make by the Clean Water Act, rather than as "technical standards". Consistent with Section 6(c) of OMB Circular A-119, EPA would not be obliged to consider the use of voluntary consensus standards as possible alternatives to the regulatory standards being adopted.

It should be noted that the effluent guideline rule (40 CFR 412) provides for voluntary alternative performance standards developed and applied in NPDES permits on a site-specific basis. CAFOs that voluntarily develop and adopt such performance standards in their NPDES permits may need to use previously approved technical

standards to analyze for some or all of the following pollutants: nitrogen, phosphorus, BOD, and TSS. Consensus standards have already been promulgated in tables at 40 CFR 136.3 for measurement of all of these analytes.

Further, the rule specifically provides that the determination of land application rates for manure is to be done in accordance with technical standards established by the State. In establishing such standards, States may rely on standards already established by USDA or other existing standards or may develop new standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

In implementing the requirements of the Environmental Justice Executive Order, EPA reviews the environmental effects of major federal actions significantly affecting the quality of the human environment. For such actions, EPA reviewers focus on the spatial distribution of human health, social and economic effects to ensure that agency decisionmakers are aware of the extent to which those impacts fall disproportionately on covered communities. EPA has determined that this rulemaking is a major federal

action. However, the Agency does not believe this rulemaking will have a disproportionate effect on minority or low-income communities. The proposed regulations will reduce the negative effects of CAFO waste in the nation's waters to benefit all of society, including minority communities.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule can not take effect until 60 days after it is published in the **Federal Register**. This will be effective April 14, 2003. This action is a "major rule" as defined by 5 U.S.C. 804(2).

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